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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,844	02/25/2002	Juan Yguerabide	11032-018-999	7432
20583	7590	03/28/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 03/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/084,844	YGUERABIDE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-15, 21-26, 28 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 16-20, 27 and 29-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group IV, claims 4, 16-20, 27 and 29-36, in the reply filed on January 10, 2005 is acknowledged. The traversal is on the ground(s) that searching groups I-VI would not place a serious burden on the examiner. This is not found persuasive because the methods of groups I-VI require different steps. As cited in the previous office action dated 10 December 2004, are drawn to different inventions and a search for each of the groups I-VI requires different search terms. Therefore, a search for any of the inventions of I-VI would not encompass a search for any of the other inventions of groups I-VI.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

2. Claims 16-20, 27 and 29-36 are objected to because of the following informalities: The claims depend from non-elected claims, e.g. claim 13. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4, 16-20, 27 and 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, part a recites detecting light from a plurality of sites, which is vague because it is unclear whether the light intensity is generated from the site or from light scattering particles within the site. Part b, recites repeating detection using one or more light filters, and it

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is vague as to whether the one or more light filters are used at once or whether detection is repeated with each of the one or more light filters. Furthermore, in part b, it is unclear how much light intensity is encompassed by “high” integrated light intensities. The term “factors” in part c is indefinite because it is unclear which factors are scaled, whether “factors” refers to numerical factors from the detection of intensity of light or physical factors of the samples at each site.

With respect to claim 18, part a is indefinite because it is unclear how the signals are divided. It is unclear whether the signals are divided by the wavelength at which the site is detected or a physical dividing aspect of the sample. Part b recites setting to zero the values from pixels, and it is unclear which values are set to zero. Furthermore, it is vague as to what is meant by the term “pixels”, it is unclear if the pixels refer to the detected sites. It is unclear how the two or more signals are combined. Claim 18 is further unclear because the claim lacks correlating steps. The preamble of the claim recites a method for scaling the signal. However, the body of the claim does not appear to scale a signal because no step of scaling is recited. It is vague as to how the scaling of the signal is performed.

Regarding claim 35, the phrase “a small volume density” is vague and indefinite because it is the amount of volume density that is encompassed by “small” is unclear.

4. Claim 18 recites the limitation "the two or more signals" in part c of the claim. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 4, 17, 18 and 31-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Phillips et al. (US 6,171,793).

Phillips et al. teach a method for providing an extended linear dynamic range in an analyte assay comprising: detecting integrated light intensities from a plurality of sites with a sensor (the probe arrays comprise a plurality of sites, col. 7, lines 1-8; col. 4, lines 42-47); repeating detection using one or more light filters such that signals generated by the sensor are linearly proportional to the integrated light at one or more of the sites with high integrated light intensities (light is detected at a first and second wavelength at each site, col. 4, lines 42-54, which is performed by including filters to detect at the specified wavelengths col. 6, lines 58-61, and a linear relationship is present between the signals and the integrated light intensity, col. 9, lines 41-59); and scaling the signals from the one or more sites by factors based on the light transmitted (col. 4, lines 55-62) by the one or more filters (col. 6, lines 58-61) to quantify the integrated light from one or more of the sites, thereby providing the extended dynamic range (col. 9, lines 50-60). Though the preamble of claim 1 recites that the light is collected from light scattering particles as signals, the body of the claim does not appear to require this limitation. Therefore, any target emitting a signal and capable of transmitting light, is capable of performing the recited method.

With respect to claim 17, the factors for scaling the signal are calculated from the transmission curve for the filter (col. 9, lines 41-49).

Regarding claim 18, Phillips et al. teach scaling the signal comprising the steps of: dividing the signals of the assay by the wavelength dependent transmission curve of the one or more filters used to collect the image (the signals are separated by the different filters required for the two different wavelengths and the transmission curves are collected, col. 9, lines 50-60); setting to zero the values from pixels that were saturated (the constant value produced by the saturated pixels can be zero; col. 9, lines 13-20; furthermore the intensity at saturation is zero for the sample shown in Fig. 8A); and combining the two or more signals (the two signals are collected from the two different filters set to transmit different wavelengths, col. 9, lines 50-60).

With respect to claims 31-36, Phillips et al. teach forming an image of one or more sites with the combined signals (col. 12, line 64-col. 13, line 6) comprising the steps of identifying background portions of the image and removing signals corresponding to the background portions of the image (col. 9, lines 35-49). Phillips et al. also teach the sensor being a photomultiplier tube (col. 6, lines 51-57). Phillips et al. further teach a plurality of sites that are separately addressable (col. 6, lines 62-67), associated with a microarray (col. 5, lines 49-53), and present in a sample of a cell (col. 8, lines 42-51).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 16, 19, 20, 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 6,171,793) in view of Bartz (US 5,350,922).

Phillips et al., as applied to claim 1, teach a method for providing an extended linear dynamic range in an analyte assay. However, Phillips et al. fail to teach one or more of the filters being a bandpass interference filter.

Bartz teaches a bandpass interference filter (col. 7, lines 8-12), in order to pass corresponding wavelength bands by fiber optic probes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Phillips et al., light from light scattering particles as taught by Bartz, in order to reduce the optical and electronic signal to noise ratio.

With respect to claims 16 and 27, Bartz teaches light transmitted by filters using a white light source (col. 6, lines 1-12). Bartz further teaches light from light scattering particles comprising light scattered by the light scattering particles (col. 3, lines 26-30).

With respect to claims 29 and 30, Bartz teaches an extended range comprising integrated light intensities quantified over at least six orders of magnitude (col. 3, lines 47-50), and the dynamic range extended by at least one order of magnitude over the dynamic range of an assay

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without the extension of the dynamic range (col. 3, lines 41-50; col. 4, lines 49-54), and the dynamic range being linear (col. 3, lines 41-46).

Regarding claim 20, Phillips et al., as applied to claim 1, fail to teach the amount of light transmitted by one or more filters. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation”

Application of *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.”

*Id.* at 458, 105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claim 20 are for any particular purpose or solve any stated problem, and the prior art teaches that the light transmitted by one or more filters can be varied in order to prevent direct transmission of light from the light source to the detector, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the detection of scattered light art.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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03/14/05